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Mr. David Kropp
Acting Director, Regulatory and Consumer Affairs
Pharmavite Corporation
P.O. Box 9606
Mission Hills, California 91346-9606

Dear Mr. Kropp:

This is in response to your letter of October 23, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission is intended to amend your previous submission of October 8, 2001. Your current submission states that Pharmavite Corporation is making the claims "Heart Healthy!" and "Cholesterol fighter" for the product Cholest-Off™, containing the ingredient Reducol™. These claims appear to represent the product as being intended to reduce blood cholesterol levels and support cardiovascular health.

In a letter to you dated October 30, 2001, we concluded that the statements being made for this product are statements about the relationship between plant sterols and stanols and the risk of coronary artery disease and are not claims subject to 21 U.S.C. 343(r)(6), but instead are claims subject to 21 U.S.C. 343(r)(1)(B). We advised you that, for several reasons, your product does not appear to meet the eligibility requirements to bear the health claim authorized in 21 CFR 101.83 in its labeling and that the claims themselves do not appear to meet the message requirements set forth in the regulation. We concluded that, therefore, since your statements are not claims under 21 U.S.C. 343(r)(6) and are also not authorized health claims under 21 U.S.C. 343(r)(1)(B), they are claims that suggest that this product is intended to treat, prevent, cure, or mitigate a disease, namely coronary artery disease. We believe that the claims that are the subject of the current submission are also claims that suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Page 2 - Mr. David Kropp

Please contact us if you require further assistance.

Sincerely,

for 

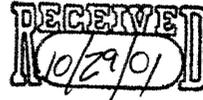
John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Compliance, HFR-PA240



October 23, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

On October 8, 2001 we submitted a notice that we were using certain statements of nutritional support on the labeling of our Cholest-off™ product. At that time, we neglected to include two statements which appear on the label. The purpose of this letter is to inform you of the use of those two statements.

- 1) Name and address of manufacturer:
Pharmavite Corporation, PO Box 9606, Mission Hills, CA 91346
- 2) Text of the statements:

Heart Healthy!
Cholesterol fighter
- 3) Name of the dietary ingredient if not provided in the text of the statements:
Plant sterols/stanols
- 4) Name of the dietary supplement:
Cholest-Off
450 mg plant sterols/stanols

The above statements may be used in one or more of the following brands of products: B.J.'s Wholesale, CVS, Duane Reade, Kirkland Signature, Jogmate, Nature Made, Nature's Resource, Optimize, Spring Valley, Walgreens.



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
October 23, 2001
Page 2

We certify the information in this notice is complete and accurate, and we have substantiation that the above statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read 'David Krepp', is written over the printed name.

David Krepp
Acting Director, Regulatory and Consumer Affairs

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